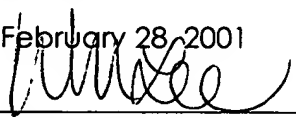




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Patent Docket P0998D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Jeffrey L. Cleland et al. Serial No.: 09/273,230 Filed: March 18, 1999 For: PROTEIN FORMULATION	Group Art Unit: 1642 Examiner: G. Bansal CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on February 28, 2001  Wendy M. Lee
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☐ **37 CFR § 1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR § 1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR § 1.114.

☒ **37 CFR § 1.97(c)**

- by the applicant after the period specified in 37 CFR § 1.97(b), but prior to the mailing date of any of a final action under 37 CFR § 1.113, or a notice of allowance under 37 CFR § 1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR § 1.17(p) **or** a statement as specified in 37 CFR § 1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 08/615,369, filed March 14, 1996 and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1 - A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the

Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR § 1.17(p).

Respectfully submitted,

GENENTECH, INC.

By: _____

Wendy M. Lee

Reg. No. 40,378

Telephone No. (650) 225-1994



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PATENT TRADEMARK OFFICE

T-630 P.01/01 F-624

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Sheet 1 of 1

PATENT & TRADEMARK OFFICE							U.S. Dept. of Commerce Patent and Trademark Office	Atty Docket No. P0998D1	Serial No. 09/273,230
FORM PTO-1449									
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)						Filing Date 18 Mar 1999			
						Group 1642			
U.S. PATENT DOCUMENTS									
Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date			
	248	6,165,464	26.12.00	Hudziak et al.					
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)									
	249	Combs et al., "Comparative efficacy of Herceptin in the nude mouse tumor xenograft model: IV bolus versus subcutaneous infusion" (Poster presented at the November 1999 AAPS National Meeting) (1999)							
	250	Kern et al., "Inhibition of human lung cancer cell line growth by an anti-p185HER2 antibody" <u>American Journal of Respiratory Cell & Molecular Biology</u> 9(4):446-454 (Oct 1993)							
	251	Ohnishi et al., "Prolonged survival of mice with human gastric cancer treated with an anti-c-ErbB-2 monoclonal antibody" <u>British Journal of Cancer</u> 71(S):969-973 (May 1995)							
	252	Tokuda et al., "In vitro and in vivo anti-tumour effects of a humanised monoclonal antibody against c-erbB-2 product" <u>British Journal of Cancer</u> 73(11):1362-1365 (Jun 1996)							
Examiner						Date Considered			
*Examiner initial if reference considered, whether or not citation is in conformance with MPEP 609, draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.									

USCOMM-DC 80-398